UNITED STATES DISTRICT COURT

for the

Southern District of New York

In re Actos Antitrust Litigation (Coordinated Actions)

Plaintiff

v.

Defendant

Civil Action No. 1:13-cv-09244-RA-SDA

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: Caremark Rx, LLC
The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801

(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material:

See the attached Schedule A.

Place:	Date and Time:
Conrad O'Brien PC 1500 Market St, Suite 3900W Philadelphia, PA 19102	04/28/2022 10:00 am

☐ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 03/29/2022

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

s/ David K. Lukmire

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Takeda Pharmaceutical Company Limited, et al., who issues or requests this subpoena, are:

David K. Lukmire (P: 215.523.8314, E: dlukmire@conradobrien.com)
1500 Market Street, Suite 3900W, Philadelphia, PA 19102

Notice to the person who issues or requests this subpoena

A notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:13-cv-09244-RA-SDA

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

SCHEDULE A

I. DEFINITIONS

1. The Uniform Definitions in Discovery Requests in Rule 26.3 of the Civil Rules for the United States District Courts for the Southern and Eastern Districts of New York are, by the express terms of Local Civil Rule 26.3, incorporated into these requests.

2. "AB-rated" means a drug product that has been deemed by the FDA as meeting the necessary requirements (as explained in the Preface to the Orange Book, 36th Edition) to be granted an AB therapeutic equivalence code and therefore marketed as interchangeable to a reference-listed drug (the branded product) as defined by 21 C.F.R. § 314.94(a)(3) and identified by the FDA.

3. "Action" means the coordinated actions pending in the United States District Court for the Southern District of New York under the caption *In re ACTOS Antitrust Litig.*, Master File No. 13 Civ. 9244 (S.D.N.Y.), which were previously captioned separately as *In re Actos End-Payor Antitrust Litig.* (No. 13 Civ. 9244) and *In re ACTOS Direct Purchaser Litig.* (No. 15 Civ. 3278).

4. "ACTOS" means all pharmaceutical products that were or are labeled, marketed, distributed, or sold under the trademark or brand name "ACTOS" (or any variant thereof), regardless of the dosage form, dissolution rate, dosage strength, packaging, or labeling, including the pharmaceutical products described in NDA No. 21073 and any supplements to NDA No. 21073.

5. "ANDA" means Abbreviated New Drug Application as defined in 21 U.S.C. § 355(j).

6. "Downstream Customer" means any entity with which You contract for the provision of prescription drug benefits, including, but not limited to, any insurance company or policy, Health Maintenance Organization, Preferred Provider Organization, Point-of-Service plans, health and welfare fund, governmental organization, employer, or physician.

7. "Direct Purchaser Plaintiffs" means Cesar Castillo, Inc., Meijer, Inc., Meijer Distribution, Inc., and any additional direct purchaser plaintiff added to the above-captioned case by transfer, consolidation, or further amendment of the Complaint, as well as all predecessors and successors thereof, any of their former or current affiliates, parents, or subsidiaries, and any of their directors or officers, as well as any employees, agents, representatives, or other Persons acting or purporting to act on behalf of the foregoing.

8. "End Purchaser Plaintiffs" means 199 SEIU-National Benefit Fund; City of Providence, Rhode Island; Crosby Tugs, LLC; International Union of Operating Engineers Local 132 Health and Welfare Fund; Man-U Service Contract Trust Fund; Minnesota and North Dakota Bricklayers and Allied Craftworkers Health Fund; NECA-IBEW Welfare Trust Fund; New England Electrical Workers Benefit Fund; Painters District Council No. 30 Health and Welfare Fund and any additional end purchaser plaintiff added to the above-captioned case by transfer, consolidation, or further amendment of the Complaint as well as all predecessors and successors

thereof, any of their former or current affiliates, parents, or subsidiaries, and any of their directors or officers, as well as any employees, agents, representatives, or other Persons acting or purporting to act on behalf of the foregoing.

9. "FDA" means the United States Food and Drug Administration, including its departments, committees, subdivisions, or individuals acting on its behalf or under its authority.

10. "Formulary" or "Formularies" means any list of prescription drugs, whether branded or generic, used by You or on Your behalf to categorize, rank, or otherwise identify prescription drugs or prescription drug coverage.

11. "Generic ACTOS" means any product that is (or has sought to be) AB-rated by the FDA for which ACTOS is the reference-listed drug.

12. "Glycemic Control" means the way of managing the blood glucose level of patients with Type 2 diabetes at an optimum level.

13. "NDA" means New Drug Application as defined in 21 U.S.C. § 355.

14. "Orange Book" means the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations."

15. "Person" means any individual or group of individuals, corporation, partnership, association, governmental entity, department, commission, bureau, or any other kind of legal or business entity.

16. "Pharmacy" means any entity, including mail order vendors and other retailers, and including hospitals and other inpatient care facilities, that dispenses pharmaceutical products to patients, including pursuant to a prescription issued by a physician or any other health care provider. (If a pharmacy has more than one retail location or outlet, each location should be treated separately.)

17. "Plaintiffs" means Direct Purchaser Plaintiffs and End Purchaser Plaintiffs, collectively.

18. "Plan" means any Plan or coverage that You operate, administer, sponsor, or insure, that pays for, purchases, reimburses (in whole or in part), dispenses, or otherwise provides pharmaceuticals to individuals.

19. "Takeda" means Takeda Pharmaceutical Company Limited, Takeda America Holdings, Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Development Center Americas, Inc.

20. "You" and "Your" means Caremark Rx, LLC, all parents, subsidiaries, affiliates, predecessors, and successors thereof, and any employee, officer, or other agent of any of the foregoing, and any other entity possessing documents responsive to the requests in this Schedule A.

II. RELEVANT TIME PERIOD

Unless otherwise specified, the discovery sought relates to the period from January 1, 2009 through December 31, 2015.

III. INSTRUCTIONS

1. The terms defined above and the individual requests for production are to be construed broadly to the fullest extent of their meaning in a good faith effort to comply with the Federal Rules of Civil Procedure.

2. As used in these requests, the singular should be read to include the plural and vice versa, and the present tense should be read to include the past tense and vice versa.

3. These requests for production are continuing so as to require supplemental responses promptly in accordance with Rules 26, 34, and 45 of the Federal Rules of Civil Procedure. Unless otherwise specified or agreed to by the parties, documents are to be produced within 30 days of the date of service hereof, and otherwise thereafter as soon as is reasonably possible after they are located or obtained.

4. If You have any good faith objections to any request or any part thereof, You shall state the specific nature of the objection and whether it applies to the entire request or to a part of the request. If there is an objection to any part of a request, then the part objected to should be identified and documents responsive to the remaining unobjectionable part should be timely produced.

6. Any alteration of a responsive document, including notes, underlining, stamps, drafts, revisions, modifications and other versions of a final document, is a separate document and is to be produced as a separate document.

7. If You contend that information responsive to any request for production is incomplete, then You must provide all responsive information of which You are now aware.

8. Each request shall be responded to on the basis of Your entire knowledge, from all sources, after a reasonable and good faith inquiry has been made and a search has been conducted.

9. Pursuant to Rule 45(e) of the Federal Rules of Civil Procedure, documents shall be produced as they are kept in the usual course of business or segregated as responsive to a specific request enumerated in this Subpoena. If documents and things are produced as they are maintained in the normal course of business: (a) all associated file labels, file headings thereon, and file folders shall be produced together with the responsive documents from each file; (b) all documents containing markings thereon that cannot be legibly or accurately copied shall be produced in their original form; otherwise, You may produce photocopies; and (c) each page shall be given a discrete production number.

10. Pursuant to Rule 45(a)(1)(C), all documents and data should be produced in the manner required by the Electronically Stored Information protocol entered in this case.

IV. REQUESTS FOR PRODUCTION OF DOCUMENTS

1. Documents sufficient to show actual or potential competition, substitutability, or interchangeability between or among ACTOS, Generic ACTOS, and other Glycemic Control treatments.

2. Documents sufficient to show efforts considered or implemented by You to encourage or discourage the prescribing or dispensing of ACTOS, Generic ACTOS, and/or any treatments for Glycemic Control, including but not limited to any evaluations by Your pharmaceutical and therapeutics committee relating to the safety and efficacy of treatments for Glycemic Control, economic and therapeutic factors considered in connection with Formulary placement, and comparisons between ACTOS, Generic ACTOS, and other treatments for Glycemic Control.

3. Documents sufficient to describe reimbursements and/or any programs that You offer or maintain with any Downstream Customer or Pharmacy to encourage or promote therapeutic substitution (either brand for brand, or generic for brand) and/or generic substitution (generic for brand), especially as it relates to ACTOS, Generic ACTOS, and other treatments for Glycemic Control.

4. Documents sufficient to describe any rebate sharing policies that You offer or maintain with Downstream Customers, including, but not limited to, sample or exemplary contracts with Downstream Customers that pertain to ACTOS, Generic ACTOS, and other treatments for Glycemic Control.

5. Documents sufficient to describe any pharmacy discounts that You receive from Pharmacies, including, but not limited to, sample or exemplary contracts with Pharmacies that pertain to ACTOS, Generic ACTOS, and other treatments for Glycemic Control.

6. Documents sufficient to show projections, estimates, models, forecasts, and/or budgets related to the expected revenue, costs, profits, royalties, or other income resulting from the therapeutic substitution (either brand for brand, or generic for brand) and/or generic substitution (generic for brand) with respect to ACTOS, Generic ACTOS, and other treatments for Glycemic Control.

7. With respect to each Plan under which You provide or have provided coverage for ACTOS, Generic ACTOS, and other treatments for Glycemic Control, documents sufficient to show any risk sharing or other agreements You have entered into regarding the pharmacy benefit, including, but not limited to, performance guarantees, rebate guarantees, pharmacy discount guarantees, overall pricing guarantees, overall cost guarantees, and capitation arrangements with Downstream Customers.

8. Documents sufficient to show any payments made or amounts received pursuant to any risk sharing or other agreements You have entered into regarding prescription drug coverage for ACTOS, Generic ACTOS, and other treatments for Glycemic Control, including, but not limited to, performance guarantees, rebates and rebate guarantees, pharmacy discount guarantees,

overall pricing guarantees, overall cost guarantees, and capitation arrangements with Downstream Customers. To the extent any such payments made or received were aggregate payments, i.e., they pertained to multiple drugs, provide information on ACTOS's share of those payments.

9. With respect to each Medicare Part D Plan under which You provide or have provided coverage for ACTOS, Generic ACTOS, and other treatments for Glycemic Control, documents sufficient to show any type of federal government reimbursement You have received, including, but not limited to, direct subsidy, risk adjustment, reinsurance, and risk corridor payments.

10. Documents sufficient to show any payments made or amounts received pursuant to any risk sharing or other agreements You have entered with Pharmacies that pertain to dispensed prescriptions for ACTOS, Generic ACTOS, and other treatments for Glycemic Control. To the extent any such payments made or received were aggregate payments, i.e., they pertained to multiple drugs, provide information on ACTOS's share of those payments.

11. Your Formularies on which ACTOS, Generic ACTOS, and other treatments for Glycemic Control are listed.

12. Documents sufficient to show the process by which You determine which drugs, including treatments for Glycemic Control, are placed on Your Formularies.

13. Documents sufficient to show Your evaluation of ACTOS, Generic ACTOS, and other treatments for Glycemic Control for placement on, or removal from, Your Formularies.

14. Documents sufficient to show the reasons for any Formulary tier designation for any treatments for Glycemic Control, including ACTOS and Generic ACTOS, and any restrictions applied to the utilization of any treatment for Glycemic Control.

15. Documents sufficient to show the actual or projected costs or utilization rates for ACTOS, Generic ACTOS, and other treatments for Glycemic Control.

16. Documents sufficient to show any step therapy or prior authorization required by You or Your customers for any drug product used for Glycemic Control, including, but not limited to, ACTOS and Generic ACTOS.

17. With respect to each Medicare Part D Plan under which You provide or have provided coverage for ACTOS and Generic ACTOS, documents sufficient to show the cost sharing amounts required from the Plan's enrollees for ACTOS and Generic ACTOS prescriptions at each coverage phase, including, but not limited to, copayment amounts, co-insurance requirements, co-insurance caps, and out-of-pocket maximums as applicable.

18. Sample or exemplary contracts in which the price charged for ACTOS, Generic ACTOS, or other treatments for Glycemic Control is determined in whole or in part by adding a markup to, or taking a reduction from, a measure of cost.

19. Documents concerning the sales and marketing of treatments for Glycemic Control, including documents pertaining to the sale of, share of sales in the therapeutic class, or competition between or among any treatments for Glycemic Control (whether branded or generic) in the United States, including but not limited to information, analyses, studies, projections, investigations, or reports concerning the actual, potential, expected, or projected sales of such products or substitution among them.

20. On a monthly basis, during the Relevant Time Period, the following data maintained by You relating to ACTOS, Generic ACTOS, and other treatments for Glycemic Control:

a. Total number of patients;

b. Total units (indicate whether by tablet or by bottle);

c. Total amount of claims in dollars; and

d. Total co-pay in dollars.

21. During the Relevant Time Period, the following prescription-level data maintained by You relating to reimbursed prescriptions for ACTOS and Generic ACTOS:

a. Claim/invoice number;

b. National Drug Code ("NDC");

c. Number of tablets dispensed;

d. Drug description (i.e., brand/generic name, drug form, drug strength);

e. Quantity dispensed (e.g., number of pills);

f. Days supply;

g. Date dispensed/date of service;

h. Ingredient cost;

i. Dispensing fee;

j. Administrative fee;

k. Total cost;

l. Member ID;

m. Member state;

n. Date of birth;

o. Amount paid by member;

p. Pharmacy name;

q. Pharmacy ID;

r. Pharmacy location (e.g., state);

s. Amount You paid to the Pharmacy;

t. Downstream Customer Name;

u. Customer ID; and

v. Amount You received from the Customer.

22. All documents You produce or have produced to Plaintiffs related to this Action.

23. All communications with Plaintiffs or counsel for Plaintiffs related to this Action.